

Research Involving Private Information or Biological Specimens

Are the specimens/data obtained from living individuals?

NO, individuals are NOT living

NOT Human Subjects Research

YES, individuals ARE living

Are the specimens/data:

- Human cell lines obtained from a commercial provider (e.g. ATCC); or
- Human cells about which all information has been published; or
- Unidentifiable specimens/data obtained from a commercial provider; or
- Unidentifiable specimens/data obtained from a provider that is prohibited from releasing identifiers by established regulations or policies*

NO

Were/will the specimens/data (be) collected specifically for the proposed research through an interaction or intervention with living individuals?

NO

Can the *recipient* link the specimens/data **directly** to identifiable living individuals?

NO

Can the *provider* link the specimens/data, directly or indirectly, to identifiable living individuals?

NO

NOT Human Subjects Research

YES

Does the *provider* meet the definition of an “investigator” in the recipient’s research?

NO, *provider* is “solely providing”

Are the specimens/data provided with a code linking them to identifiable living individuals?

NO

NOT Human Subjects Research

YES

Can the *recipient* readily ascertain the identities of the individuals to whom the specimens/data pertain? Examples of situations in which the recipient **cannot** link the specimens/data to living individuals include:

- the key to decipher the code is destroyed before the research begins; or
- the investigators and the holder of the key to the code enter into an agreement preventing the release of the key to investigators under any circumstances; or
- there are IRB-approved written policies in place preventing the release of the key under any circumstances; or
- there are other legal requirements prohibiting the release of the key under any circumstances*.

NO

NOT Human Subjects Research

YES

Human Subjects Research

* Because NIH is not a covered entity, NIH cannot comment on the adequacy with which institutions address HIPAA requirements. NIH, therefore, cannot recognize the HIPAA Privacy Rule as the regulation preventing the release of identifiers.